

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BENTLEY A. HOLLANDER	:	CIVIL ACTION
	:	
v.	:	
	:	
B. BRAUN MEDICAL, INC.	:	NO. 10-835

MEMORANDUM

McLaughlin, J.

April 12, 2011

The plaintiff, Bentley A. Hollander, filed this *qui tam* relator suit on behalf of the United States against defendant B. Braun Medical, Inc., for violations of the False Marking Statute, 35 U.S.C. § 292. The defendant filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). In his opposition to the motion, the plaintiff attached a proposed amended complaint.¹ The Court invited supplemental briefing on the Federal Circuit's recent decision, In re BP Lubricants USA Inc., 2011 U.S. App. LEXIS 5015 (Fed. Cir. Mar. 15, 2011), and held oral argument on April 8, 2011. For the following reasons, the Court will grant in part and deny in part the motion to dismiss the amended complaint.

¹The Court concludes that the plaintiff's original complaint fails the heightened pleading set forth in the Federal Circuit's recent decision, In re BP Lubricants USA Inc. The Court therefore grants the plaintiff's request to file the amended complaint attached to his opposition. The Court will treat the parties' supplemental briefing as relating to the amended complaint.

I. Facts as Alleged in the Amended Complaint²

Defendant B. Braun Medical, Inc. ("Braun") is a global healthcare products company, which specializes in the manufacture of intravenous (IV) therapy medications and solutions. Many of the defendant's IV solutions are distributed in sterile containers that bear the trade name "Excel." The defendant's product literature and labeling information identify "Excel" as a registered trademark of Braun, and refer to U.S. Patent No. 4,803,102 ("102 Patent"), which was issued on February 7, 1987, and which expired on October 27, 2007. The defendant has also marked certain products with U.S. Patent No. 4,491,589 ("589 Patent"), which was issued on January 1, 1985, and which expired on April 29, 2003. Am. Compl. ¶¶ 9, 19-22, 813-14.

As a highly sophisticated business entity, the defendant has extensive experience applying for, procuring, and publishing its patents. The defendant also employs patent attorneys who manage its intellectual property and monitor the

²In evaluating a motion to dismiss under Rule 12(b)(6), a court must accept all well-pleaded facts as true, and must construe the complaint in the light most favorable to the plaintiff. Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009). When evaluating a motion to dismiss, the court should disregard any legal conclusions. The court must then determine whether the facts alleged are sufficient to show that the plaintiff has a "plausible claim for relief." Fowler, 578 F.3d at 210. If the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, then the complaint has alleged, but it has not shown, that the pleader is entitled to relief. Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2008).

expiration dates of its patents. The defendant actively litigates to protect its patent rights, and has prevailed in patent infringement suits in the past. As a consequence, the defendant knows when each of its patents expires. Am. Compl. ¶¶ 9, 13-14, 16-17.

Although the '589 and '102 Patents expired in 2003 and 2007, respectively, the defendant has continued to mark its products with the expired patents. The defendant has also updated its product packaging since the patents in question expired, and in some instances, since the present suit was filed, but has failed to remove the expired patent numbers from the packaging. Am. Compl. ¶¶ 26-28

The defendant specifically knew the expiration dates of the '102 and '589 Patents because it was not the assignee of those patents. Instead, the defendant paid licensing fees for the use of the patents and accordingly monitored their expiration dates. The defendant has also cited to the '102 Patent in several of its own patents filed with the United States Patent and Trademark Office ("USPTO"), including one patent that was filed after the '102 Patent had expired. As a consequence, the defendant was familiar with the '102 Patent's expiration date. Am. Compl. ¶¶ 22-25.

The plaintiff asserts eighty-five counts against the defendant based on its alleged false marking of the '102 and '589

Patents. Only two of the counts, LXXII and LXXIII, relate to the '589 Patent, and the remaining eighty-three counts assert false marking of the '102 Patent. Each of the counts is substantively identical, although the allegations relating to the defendant's product packaging updates vary in detail between the counts.

II. Analysis

A. Applicable Law

The False Marking Statute, 35 U.S.C. § 292, prohibits the false marking of a product with a patent "for the purpose of deceiving the public." To state a claim for false marking under § 292, a plaintiff must establish (1) the marking of an unpatented article; (2) with the intent to deceive the public. Forest Group, Inc. v. Bon Tool Co., 590 F.3d 1295, 1300 (Fed. Cir. 2009).

Neither party disputes the first element - the marking of an unpatented article.³ Instead, the parties disagree over whether the requisite "intent to deceive" is present. An inference of intent to deceive can be drawn where a plaintiff shows "the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity." Clontech Labs, Inc. v. Invitrogen Corp., 406 F.3d 1347, 1352-53 (Fed. Cir.

³ An article covered by an expired patent is "unpatented" within the meaning of § 292(a). Pequignot v. Solo Cup Co., 608 F.3d 1356, 1361 (Fed. Cir. 2010).

2005). The combination of a false statement and knowledge that the statement was false creates a rebuttable presumption of intent to deceive. Pequignot v. Solo Cup Co., 608 F.3d 1356, 1362-63 (Fed. Cir. 2010).

In a recent decision, the Court of Appeals for the Federal Circuit held that the heightened pleading standard set forth in Federal Rule of Civil Procedure 9(b) applies to false marking claims. In re BP Lubricants USA Inc., 2011 U.S. App. LEXIS 5015 (Fed. Cir. March 15, 2011). To establish intent to deceive under § 292, a plaintiff must plead facts supporting an inference of a "purpose of deceit, rather than simply knowledge that a statement is false." Id. at *10 (citations omitted). These facts must be pled with particularity, which means that a plaintiff must allege "the specific who, what, when, where, and how" of the alleged fraud. See id. at *4 (citing Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009)).

In BP Lubricants, the Federal Circuit rejected as conclusory the plaintiff's allegations that the defendant was a "sophisticated company and ha[d] experience applying for, obtaining, and litigating patents." Id. at *10. The Court noted that this "bare assertion" provided "no more of a basis to reasonably distinguish a viable complaint than merely asserting the defendant should have known the patent expired." Id.

The Federal Circuit also outlined examples of allegations that might permit a court to draw an inference of intent to deceive. For instance, a plaintiff can “allege that the defendant sued a third party for infringement of the patent after the patent expired or made multiple revisions of the marking after expiration.” Id. at *12.

B. Whether the Plaintiff has Pled Intent to Deceive

The defendant argues that the plaintiff has failed to plead with particularity as required by Rule 9(b). According to the defendant, the amended complaint contains the same sort of allegations relating to the defendant’s “sophistication” that the Federal Circuit rejected as conclusory in BP Lubricants. In opposition, the plaintiff argues that allegations of multiple product packaging updates, some of which occurred after the defendant was put on notice of its expired patents based on the present suit, support an inference of intent to deceive. The Court will grant in part and deny in part the motion to dismiss.

1. The ‘102 Patent

The Court will grant the motion to dismiss as to Counts VIII-IX (8-9), XLVIII-LII (48-52), LVI-LVII (56-57), LXV-LXVI (65-66), LXX-LXXI (70-71), and LXXIV-LXXXI (74-81). These counts contain only conclusory allegations that the defendant was

sophisticated, it “knew” that the ‘102 Patent had expired, and it decided to continue marking its products with the expired patent “for the purpose of deceiving the public.” See, e.g., Am. Compl. ¶¶ 129-131. In each of these counts, the plaintiff also avers generally that, “[i]n spite of the expiration of the ‘102 Patent, Braun published new product packaging containing the ‘102 Patent.” Id. ¶ 127.

These allegations do not contain the requisite “who, what, when, where, and how” necessary to satisfy Rule 9(b). As the Federal Circuit explained in BP Lubricants, allegations that a defendant is sophisticated and therefore knew that its patents were expired cannot support an inference of intent to deceive. Similarly, the plaintiff’s allegations that the defendant “published new product packaging” are devoid of the detail necessary to plead with particularity. For instance, the plaintiff has not alleged what these product packaging updates entailed, whether the packaging was revised a single time or multiple times, and the time frame during which these updates occurred. These general averments therefore do not provide the “specific underlying facts” from which the Court can infer a “purpose of deceit.” BP Lubricants, 2011 U.S. App. LEXIS at *13.

The Court will also grant the motion to dismiss as to Counts LXXXII-LXXXV (82-85). In each of these counts, the plaintiff repeats the allegations noted above, and also avers

that "Braun published new product packaging containing the '102 Patent on December 4, 2008." Am. Compl. ¶ 127. The Court concludes that allegations of a single packaging update in 2008 are insufficient to establish intent to deceive. The plaintiff has pled no facts indicating that the defendant had actual knowledge that its patents had expired and purposefully decided to mark its products with an expired patent. In view of the fact that the '102 Patent expired in 2007, the packaging update in 2008, which failed to remove the '102 Patent, tends to support an inference of negligence rather than purposeful deception.

This Court's analysis is consistent with the analysis of other courts that have considered the issue. In particular, courts have generally found allegations of a single package revision, without more, to be insufficient to establish intent to deceive. In contrast, allegations of multiple product packaging updates, particularly where such allegations are coupled with "other indicia of the defendant's knowledge of a patent's expiration," have been deemed sufficient to establish intent to deceive. See generally Hollander v. Ortho-McNeil-Janssen Pharms., Inc., 2011 U.S. Dist. LEXIS 36890, at *16 (E.D. Pa. Apr.

4, 2011) (collecting cases).⁴ Because the plaintiff has alleged a single product update and no additional facts, the Court will grant the motion to dismiss as to Counts LXXXII-LXXXV.

The Court will deny the motion to dismiss as to all remaining counts, with the exception of Counts LXXII (72) and LXXIII (73), which relate to the '589 Patent. In the remaining counts, the plaintiff alleges that the defendant updated its product packaging multiple times after the '102 Patent expired. The plaintiff also avers that at least one of the revisions alleged in each of the remaining counts occurred after the present action was filed.

The Court concludes that these allegations are sufficient to satisfy Rule 9(b). The Federal Circuit in BP Lubricants noted that allegations of "multiple revisions of the marking after expiration" may be sufficient for a court to infer intent to deceive. BP Lubricants, 2011 U.S. App. LEXIS at *12. In the present action, the plaintiff has alleged multiple revisions, some of which occurred after this action was filed.

⁴The Court's analysis is unaffected by allegations that the defendant was a licensee of its patents, and therefore "kept close track of the terms of the Patents." These allegations are conclusory and offer no details with respect to when any licensing payments were made, or whether such payments were made in close proximity to the expiration of the patents, such that the defendant was arguably on notice. In addition, the plaintiff's allegation that the defendant cited to the '102 Patent in its USPTO filings fails to establish intent to deceive. At most, such allegations suggest that the defendant was generally aware of the '102 Patent after it had expired.

The filing of this suit arguably put the defendant on notice that its patents had expired. Accepting as true the allegation that the defendant revised its packaging after this suit was filed, and yet failed to remove the expired patent markings, the Court could infer that the defendant intended to deceive the public.⁵ See Brinkmeier v. Graco Children's Prods., 684 F. Supp. 2d 548, 551 (D. Del. 2010) (finding sufficient allegations of intent to deceive where plaintiff alleged that defendant revised its markings three times after patent had expired and was involved in infringement suit relating to patent in question).

The Court notes the ambiguity inherent in allegations of "product packaging updates." Although the Federal Circuit suggested that "multiple revisions of [a] marking" may be sufficient to establish intent to deceive, the terms "revision" and "marking" are left undefined. It is unclear whether revisions to a marking encompass only changes to the actual patent number itself, changes to the product's outer packaging, or even revisions to instruction pamphlets accompanying a

⁵The Court is not entirely persuaded that it is plausible to prove intent to deceive based solely on evidence that a defendant revised its packaging after being sued, but did not remove expired patent markings. In view of the significant penalties authorized by § 292, as well as the public notice function that a lawsuit serves, it is difficult to imagine that a defendant would leave expired patents on its products for the purpose of deceiving the public after it has been sued for false marking. Such conduct may be more consistent with gross negligence than purposeful deception. Nonetheless, BP Lubricants appears to deem these allegations sufficient to survive a motion to dismiss.

product. As the defendant noted at oral argument, it is unclear whether revisions to an instruction pamphlet that does not contain a patent marking, but which is part of a product's overall "packaging," would constitute a revision under BP Lubricants.

The Court is unable to resolve these questions at this juncture, because it would require a level of parsing that is inappropriate for the motion to dismiss stage. In addition, if the Court were to require greater specificity in the complaint, it would place too great a burden on the plaintiff at a point in the litigation where no discovery has taken place.

2. The '589 Patent

Finally, the Court will grant the motion to dismiss as to Counts LXXII (72) and LXXIII (73), which relate to the '589 patent. These counts contain only general allegations regarding the defendant's sophistication. In addition, the plaintiff avers that the defendant updated its product packaging, but provides no additional details or dates. For the same reasons articulated above, the Court concludes that these counts fail the Rule 9(b) heightened pleading standard.

III. Conclusion

For the foregoing reasons, the Court will grant in part and deny in part the motion to dismiss the plaintiff's amended complaint.

An appropriate order shall issue separately.